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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,630	09/21/2001	Peter Knox	PA 9847	5704

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AMERSHAM BIOSCIENCES
PATENT DEPARTMENT
800 CENTENNIAL AVENUE
PISCATAWAY, NJ 08855

EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,630

Applicant(s)

KNOX ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the environment" in 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 2, suggests an assay method but the claim is incomplete. (Any assay for detection of an analyte or quantitation of an analyte has to have a contact step between sample and reagent(s); a measuring step; and a correlation step. None of these steps are recited.)

Claim 3 claims a competition assay, but does not claim a competing reagent or competing analyte and does not claim with what it is competing.

Claim 4 claims a hybridization assay but does not claim whether a nucleic acid is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Balamore, WO 95/27438.

Balamore discloses an in vitro method (see page 9, lines 26-30) comprising labeling a biological molecule with hyperpolarized ^{129}Xe (see page 6, lines 12-20), and observing a magnetic resonance spectrum (NMR) and/or NMR image of the hyperpolarized xenon in the environment of the biological molecule (see page 7, lines 6-12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al., 6,090,800, in view of Weissleder et al., 6,511,967.

Unger et al. disclose the invention substantially as claimed. More specifically, as to claim 1, and claim 2 in light of the 112 rejection above, Unger et al. disclose a method comprising labeling a biological molecule with hyperpolarized ^{129}Xe (see column 57, line 24), and observing a magnetic resonance spectrum (NMR) and/or NMR image (see column 55, lines 43-47 ; and see column 82, lines 66 – column 83, line 5) of the hyperpolarized xenon in the environment of the biological molecule.

As to claim 5, the molecule is a peptide or a protein, see column 23, lines 32-53.

As to claim 6, the hyperpolarized xenon is enriched at a level of 40% or more (see column 4, lines 62-67.)

However, Unger does not explicitly disclose that the hyperpolarized xenon is used as part of an in vitro method.

Unger however does teach the use of steroid prodrugs of the invention in vivo or in vitro for providing prolong or depot action effects of the steroid (see column 12, lines 36-42.)

The use of the prodrugs for in vitro application is reiterated in Unger's definition of the terms used in the disclosure, as follows: the term "bioactive agent" refers to substances which are capable of exerting a biological effect in vitro and/ or in vivo (see column 5, lines 62-64); the term "delivery vehicle" refers to a composition, substance or material that is capable of transporting or carrying in vivo or in vitro a bioactive agent (see column 6, lines 15-18); the term "targeting ligand" refers to any material or substance which may promote targeting of tissues and/or receptors in vivo or in vitro (see column 10, lines 7-9).

Furthermore, Unger teaches that the prodrugs can incorporate stabilizing materials or vesicles (see column 18, lines 18-20) and that the stabilizing materials and/or vesicles may be used in combination with various contrast agents for imaging (see column 55, lines 34-42.) In column 55, lines 43-47, Unger teaches that the diagnostic imaging may include MRI.

In column 57, lines 16-31, Unger teaches that contrast agents suitable for the invention include hyperpolarized xenon, and then MR imaging may then be employed. Unger teaches that hyperpolarized xenon may be employed as a component within the vesicle and gives an example of an in vivo application (see column 57, lines 23-31.)

Unger also teaches that the invention can be applied for in vitro use, such as cell culture applications (see column 82, line 66 – column 83, line 2.)

Weissleder et al. teach in vitro magnetic resonance imaging of a cell line, see column 25, lines 36-43. Thus, since both Unger and Weissleder et al. teach an in vitro method using cell culture, and Weissleder et al. teach that MRI can be used for imaging the cell culture, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the MRI technique using hyperpolarized xenon as taught by Unger may be used for imaging not only an in vivo method, but also an in vitro method, as taught by Weissleder et al.

And as to claims 7-9, Unger also does not disclose that the degree of hyperpolarisation is 8% or more, or that the method is performed in a solution wherein the solvent has a viscosity in the range of 700 to 1500 mPs, or that the pressure of the xenon gas being at least 5 bar.

As to claim 7, it would have been obvious matter of design choice to modify the Unger reference by having the degree of hyperpolarisation be 8% or more since applicant has not disclosed that having the this percentage of hyperpolarisation solves any stated problem or is for any particular purpose and it appears that this percentage of hyperpolarisation would perform equally well as at a hyperpolarisation of a slightly different percentage (see for example column 57, lines 23-25.)

As to claim 8, it would have been obvious matter of design choice to modify the Unger reference by performing the method in a solution wherein the solvent has a viscosity in the range of 700 to 1500 mPs since applicant has not disclosed that the solvent in this viscosity solves any stated problem or is for any particular purpose and it appears that this viscosity would perform equally well as at a slightly different viscosity (see for example, column 31, lines 43-45.)

As to claim 9, it would have been obvious matter of design choice to modify the Unger reference such that the pressure of the xenon gas is at least 5 bar since applicant has not disclosed that pressure at this level solves any stated problem or is for any particular purpose and it appears that this pressure would perform equally well as at a slightly different pressure (see for example, column 31, lines 26-31.)

Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum of workable ranges involves only routine skill in the art (In re Aller, 105 USPQ 233.)

Allowable Subject Matter

Claims 3 and 4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: a method comprising labeling a molecule with hyperpolarized ^{129}Xe and observing a NMR image of it wherein the method is a competition assay, immunoassay, hybridisation assay or binding assay, was not found in the prior art search.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

The above rejection shows that it would have been obvious to use hyperpolarized xenon for imaging not only as part of an in vivo method, but also as part of an in vitro method.

Conclusion

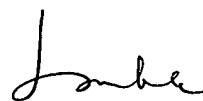
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

11/21/03